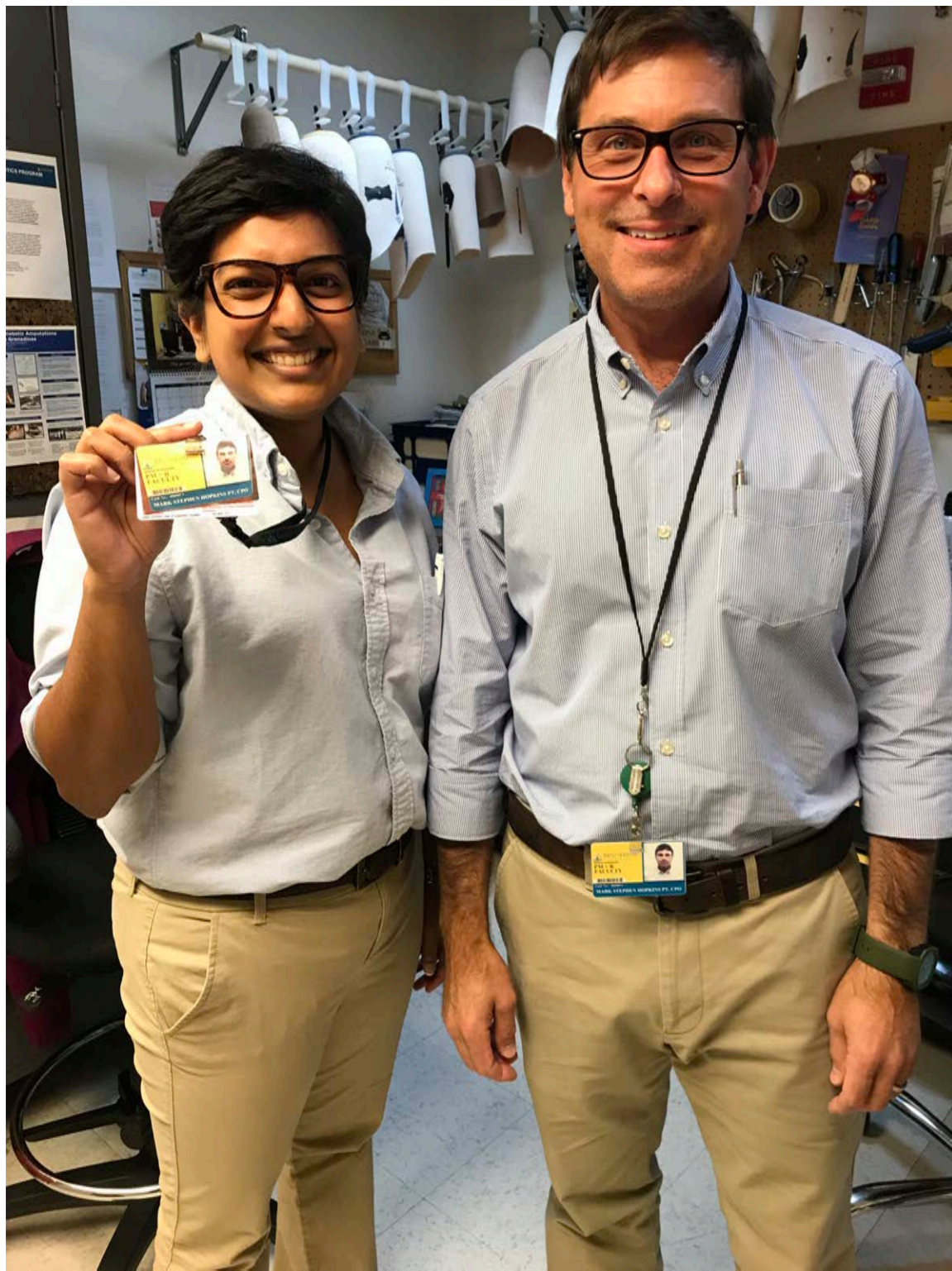




MICROPROCESSOR KNEES: AN UPDATE! (PART I)

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A bit about me...

EVALUATION FOR A PROSTHESIS

- What do you think is important?
- Who is a candidate for a prosthesis?
- How do we decide who gets which components and what type of design?
- Can you pick one most important factor for evaluation and prescription?



MULTIDISCIPLINARY REHABILITATION CLINICS

- Ideally your patient can visit a multidisciplinary rehabilitation clinic to address prosthetic care and needs as a team
- Normally PT will perform AMP or AMPnoPro with patient
- Evaluation and prescribing prosthesis for patient
- Acquiring prescription and supporting clinical documentation that backs up the recommendation made

MULTIDISCIPLINARY REHABILITATION CLINICS



- Role of physician: medical/surgical management
- Role of physical therapist: functional assessment, training
- Role of prosthetist: prosthesis specific assessment and education

AMPUTEE FUNCTIONAL LEVELS (K-LEVELS)

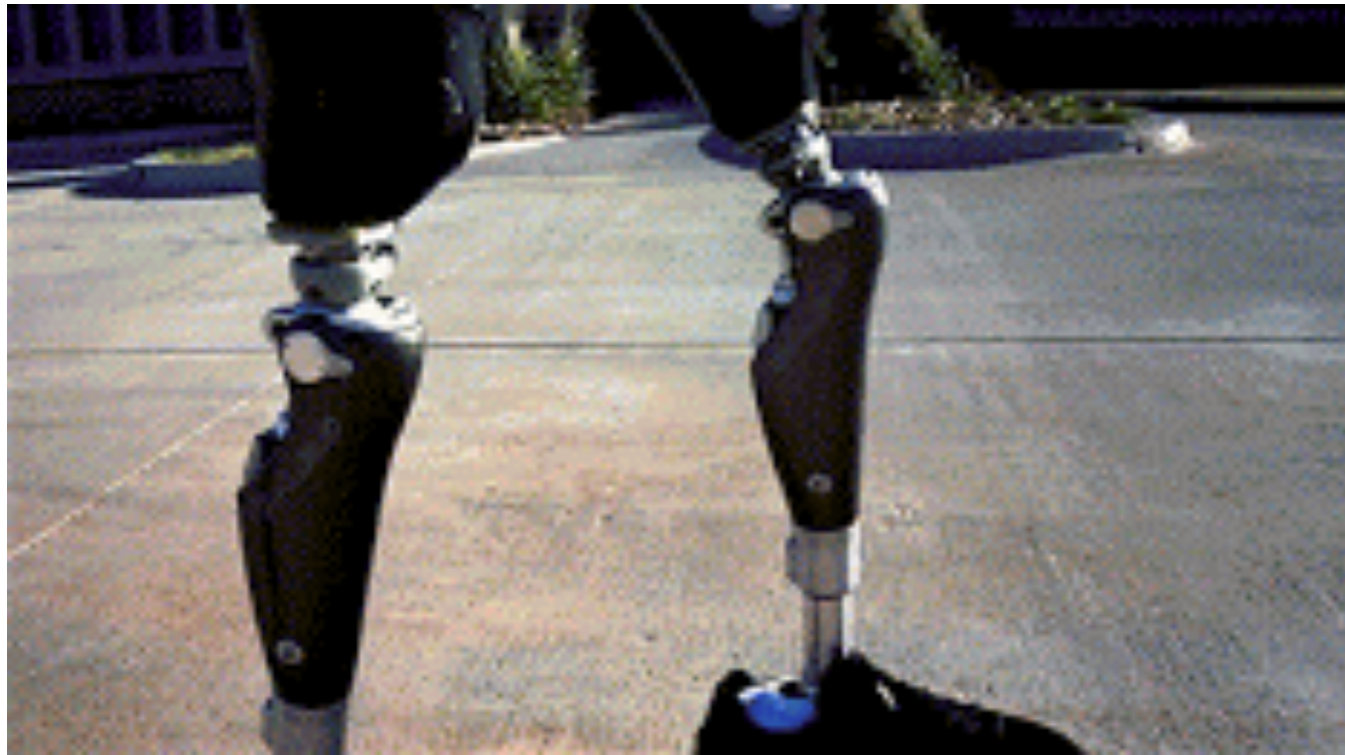
- Medicare Functional Classification Levels
- **Level 0:** Not a prosthetic candidate
- **Level 1:** Transfers and low level ambulation
- **Level 2:** Household and limited community distance ambulation
- **Level 3:** Community distances: variable cadence, can traverse environmental barriers
- **Level 4:** High impact/stress (child/high level athlete)
- **Based on previous and current function, desire to ambulate, and medical history**

COMPONENT LIMITATIONS BASED ON K-LEVELS

MFCL Level	Foot/Ankle Assembly	Knee Units
0	Not eligible	Not eligible
1	SACH or single axis only	No fluid control
2	Flexible keel or multi-axis	No fluid control
3	Any foot/ankle assembly	Most knee units (No High Activity Knee Frames)
4	Any foot/ankle assembly	Any knee unit

OUTCOME MEASURES (PHYSICAL PERFORMANCE: OBJECTIVE)

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- Amputee Mobility Predictor (AMP)
- Timed Up and Go (TUG)
- L-Test
- Berg Balance Scale
- Timed walk test (2 and 6 minute)
- Instrumented Gait Analysis

OUTCOME MEASURES (SELF-REPORTED: SUBJECTIVE)

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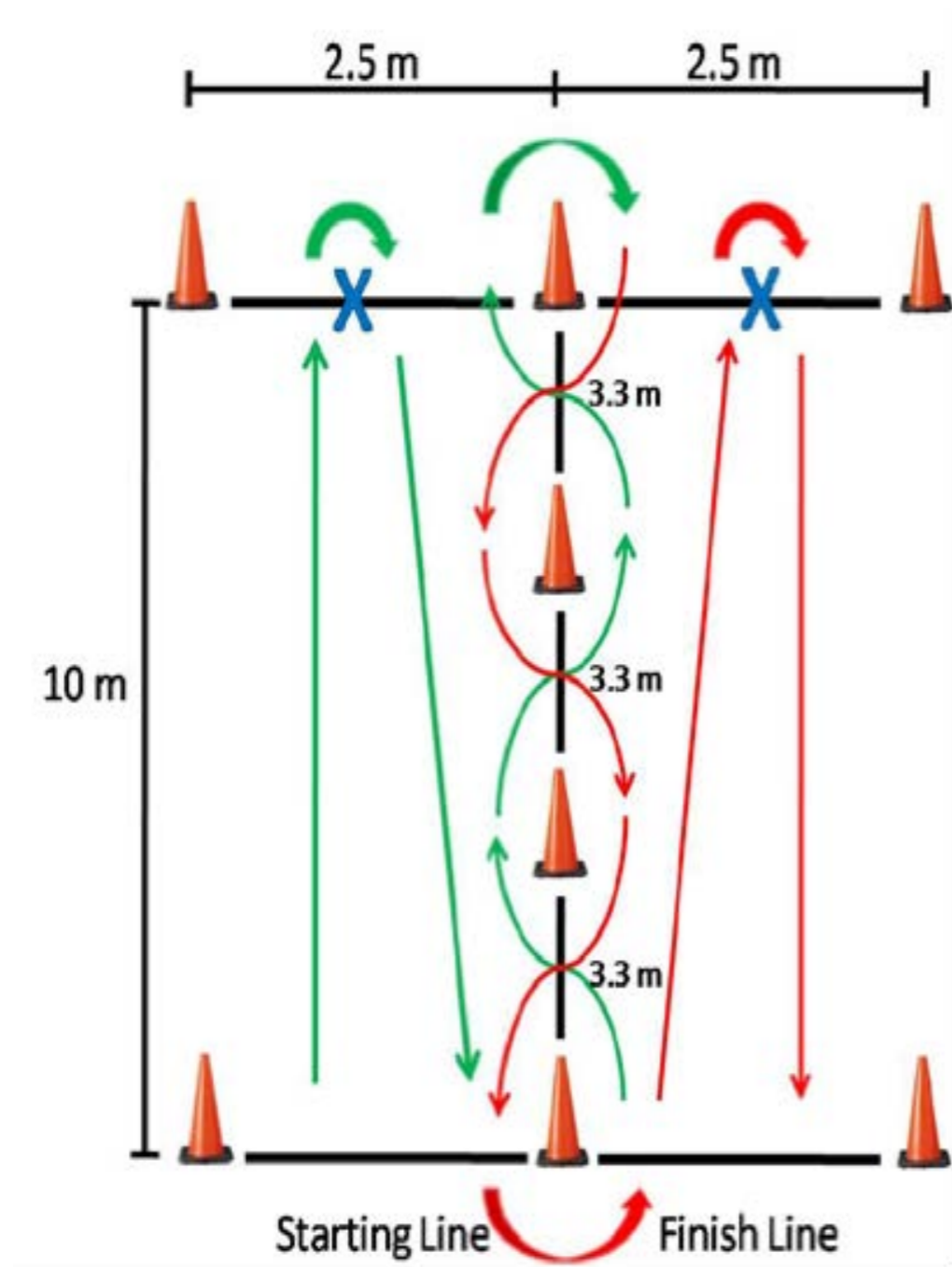
- Prosthetic Limb Users Survey (PLUS-M)
- Orthotic and Prosthetic User's Survey (OPUS)
- Prosthetic Evaluation Questionnaire (PEQ)
- Activity-Specific Balance Confidence Scale (ABC)

AMPUTEE MOBILITY PREDICTOR (AMP)

- 21 items, 20 functional tasks
- Items 1 and 2: Sitting balance
- Items 3-5: Chair to chair transfer
- Items 6-13: Standing balance
- Items 14-20: Gait quality
- Item 21: Assistive device?
- Tasks get progressively harder, patient is allowed to refuse tasks or you can skip what is contra-indicated



COMPREHENSIVE HIGH ACTIVITY MOBILITY PREDICTOR (CHAMP)



- Measure of agility
- Turns, going from lying down to standing up, running backwards
- Takes about 20 minutes to administer



FACTORS TO CONSIDER

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- Medical and functional history
- Patient height/weight
- Patient goals (Back to work? Running? Transfers?)
- Family support
- Cognition
- Condition of limb (length, skin quality, ROM, bony prominences, heat sensitivity, pain)
- Upper limb function
- What else???





LITERATURE UPDATE

Because words are cheap

"DOES A MICROPROCESSOR-CONTROLLED PROSTHETIC KNEE AFFECT STAIR ASCENT STRATEGIES IN PERSONS WITH TRANSFEMORAL AMPUTATION?"

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- Most individuals with transfemoral amputation use other strategies to climb stairs: step-to-step (one stair at a time), or skip-step (2 stairs at a time)
- N=14 individuals with transfemoral amputation. Mean age 25 years. At least 6 months postamputation and have been walking without an assistive device for at least 3 months.
- Individuals had either microprocessor controlled knee (C-leg) or Total Knee (mechanical knee)
- Wore the Otto Bock X2 for 130 days prior to study to become acclimated (what is the acclimation period for a new knee or component?)
- Ascended 16 step staircase at 1) self-selected method and 2) step-over-step at cadence of 80 steps a minute. 3 trials

RESULTS

- Conventional knee: 10 of 14 used step-to-step strategy. 3 of 14 used skip-step strategy. 1 of 14 used step-over-step strategy.
- X2 knee: 2 of 14 used step-to-step strategy. 2 of 14 used skip-step strategy. 10 of 14 used step-over-step strategy.
- Conclusion: With X2 knee, stair ascent is more symmetrical but still deviations compared to individuals without amputations.
- Limitations: sample size and confounding factor of allowing handrail use

"BENEFITS OF MICROPROCESSOR-CONTROLLED PROSTHETIC KNEES TO LIMITED COMMUNITY AMBULATORS: SYSTEMATIC REVIEW"

- Systematic review of randomized/nonrandomized clinical trials to compare NMPK and MPK interventions in K2 patients with unilateral transfemoral amputation focusing on 3 areas
 - 1) Falling
 - 2) Independent lifestyle
 - 3) Taking on/avoiding ADLs (life satisfaction. Does my prosthesis affect my behavior in the activities I choose to do?)

CONCLUSIONS

- Using MPKs for K2 patients with unilateral transfemoral amputations may reduce falls, risk of falling, improve balance, and be able to participate in more K3 activities in the community
- Recommendation of using trial fittings in K2 patients (higher K2) to assess if MPK would benefit them
- Suggested criteria of 2 minute walk test, AMP, TUG, ABC, but there is no true definitive answer of which K2 patients would benefit from MPK
- Limitations: Low number of K2 patients over studies (N=57), no trend of outcome measures makes grouping/comparisons challenging

"ECONOMIC BENEFITS OF MICROPROCESSOR CONTROLLED PROSTHETIC KNEES: A MODELING STUDY"

- "Risk of major injurious falls is reduced by 79% in MPK users compared to NMPK users"
- 11 lives would be saved by MPK if 1000 amputees were observed for a year, based on fall-related deaths
- MPK reduce moment about the knee, a way to measure the force absorbed the knee (less force transmitted to the residual limb) --> based on expert opinion, onset of OA would be reduced from 20 to 14 persons out of 100 in 10 year period
- 10% improvement in quality of life per results from the PEQ over 10 year period
- Quality adjusted life years (QALYs): Per 100 MPK users had 102 more QALYs compared to NMPK. Number of life years increases by 14 years per 100 MPK users.

LIMITATIONS AND FUTURE RESEARCH

- There are NO randomized clinical trials comparing NMPK and MPK
- Small sample sizes in studies that were used
- No studies incorporate other factors such as "obesity, diabetes, and cardiovascular disease. The lack of studies on these long-term outcomes could potentially lead to an under-estimation of the economic impact of MPK."
- Study ages 38-62, and K3/K4, so perhaps the results are not representative of the population we actually see
- Incremental cost-effectiveness ratio is \$11,606 per QALY (which is below the generally accepted rule of \$50,000 per QALY)
(RECHECK)

"FUNCTIONAL ASSESSMENT AND SATISFACTION OF TRANSFEMORAL AMPUTEES WITH LOW MOBILITY (FASTK2):
A CLINICAL TRIAL OF MICROPROCESSOR-CONTROLLED VS. NON-MICROPROCESSOR-CONTROLLED KNEES"

- Will limited community ambulators benefit from MPK?
- N = 50 unilateral transfemoral amputees. Mean age 69 years old. Tested with conventional knee, then MPK (10 week acclimation period), then conventional knee again
- Excluded if any prosthetic adjustments in last 90 days or history of chronic skin breakdown.
- Randomly assigned MPK knee (OttoBock Compact, Ossur Rheo 3, Endolite Orion 2, Freedom Innovations Plie 3)
- Free-living environment patient function (sensors attached to waist, thighs, bilateral ankles). 8 hours of wear to count as a day.

"FUNCTIONAL ASSESSMENT AND SATISFACTION OF TRANSFEMORAL AMPUTEES WITH LOW MOBILITY (FASTK2):
A CLINICAL TRIAL OF MICROPROCESSOR-CONTROLLED VS. NON-MICROPROCESSOR-CONTROLLED KNEES"

- Significant reduction in falls with use of MPK (median falls went from 2 with non MPK, to 0 with MPK, back up to 3 with non MPK)
- Significantly less time when sitting with MPK
- Significant improvement in PEQ satisfaction scales with MPK
- Conclusion: "Provision of a MPK to patients with a TFA and low, i.e. K2, mobility will result in improved function in the free-living environment, a reduction in falls, and, subsequently, improved patient satisfaction."

"DUAL-TASK STANDING AND WALKING IN PEOPLE WITH LOWER LIMB AMPUTATION: A STRUCTURED REVIEW."

- Stems from premise of patients saying they need to concentrate on every step (anecdotally, absolutely)
- Capacity theory: With X amount of cognitive processing and doing 1 or more tasks at the same time that exceeds X amount, performance quality of 1 or more tasks declines
- Bottleneck theory: Doing 1 or more tasks at the same time leads to "processing interference" in which one task is actually prioritized (action on the other tasks is postponed)
- If more of your cognitive resources are being taken up by simply walking, less available to do other tasks (thinking about terrain, stairs, etc)

"DUAL-TASK STANDING AND WALKING IN PEOPLE WITH LOWER LIMB AMPUTATION: A STRUCTURED REVIEW."

- Objectives: Looking at research studies that investigate dual-task methods regarding walking and standing in people with lower limb amputations, and effect of MPK on dual-task walking
- "Current research does not support the hypothesis that dual-task interference during walking is greater in people with LLA compared to controls."
- "Cognitive demand did not increase during walking in people with LLA compared to controls..."
- Some evidence that using MPK reduces dual-task interference in people with mobility limitations
- Limitations: cause of amputation and age were not reported in many studies reviewed

SIMILARITIES AND DIFFERENCES ACROSS VARIOUS KNEES



Let's group these things!

MICROPROCESSOR KNEES

- Ossur Rheo
- Otto Bock C-Leg
- Otto Bock Genium
- Otto Bock X3
- Freedom Innovations Plié
- Endolite Orion
- (K2) Otto Bock Kenevo and C-leg Compact

OSSUR RHEO

- IP34. Ok for freshwater splashes
- Max weight limit 300 lbs. If jogging, 242 lbs.
- Weight of knee = 3.56 lbs
- Battery life ~ 72 hours
- 36 month limited warranty
- Magnetorheological fluid: magnetic field applied to fluid, causing particles to align in a particular way, increasing/decreasing viscosity and allowing changes in resistance for various activities



ENDOLITE ORION

- Pneumatic microprocessor control
- IP rating (????) Ok for freshwater splashes. "Weatherproof"
- Max weight limit 275 lbs
- Weight of knee = 3.3 lbs
- Battery life ~ 72 hours
- 36 month warranty



FREEDOM INNOVATIONS PLIE



- ▶ IP 67. Can be submersed in shallow fresh water for 30 minutes at a time. Should be dried off after.
- ▶ Max weight limit = 275 lbs. High activity = 220 lbs
- ▶ Weight of knee = 2.7 lbs
- ▶ Battery life ~ 24 hours
- ▶ 36 month warranty

OTTO BOCK C-LEG (4)

- ▶ IP67 rating. Water tolerance: Should not come into contact with salt water. Ok for freshwater rinse and dry immediately afterward.
- ▶ Max weight limit = 300 lbs.
- ▶ Weight of knee = 2.8 lbs
- ▶ Battery life ~ 40-50 hours
- ▶ 36 month warranty



OTTO BOCK GENIUM

- IP 54. Water tolerance: "Weatherproof". Ok for freshwater splashes.
- Max weight limit = 330 lbs
- Weight of knee = 3.09 lbs
- Battery life ~ 120 hours
- 36 month warranty
- Overcoming obstacles: Lift extended prosthesis off the ground, briefly extend the hip and quickly flex the hip (causes knee to flex for clearing obstacles/stairs more easily)
- Walk to run feature



OTTO BOCK X-3

- ▶ IP 68. Waterproof. Corrosion resistant. OK for saltwater/chlorinated water exposure/submersion.
- ▶ Max weight limit = 275 lbs
- ▶ Weight of knee = 3.8 lbs
- ▶ Battery life ~ 120 hours (5 days)
- ▶ 36 month warranty
- ▶ Overcoming obstacles: Lift extended prosthesis off the ground, briefly extend the hip and quickly flex the hip (causes knee to flex for clearing obstacles/stairs more easily)
- ▶ Walk to run feature



OTTO BOCK KENEVO (K2 MPK)

- Designed for more support for sit to stand transitions, and those with a shuffling gait pattern (shorter step length)
- Walking speed NOT beyond 3 km/hour
- IP22 rating: Dripping water
- Max weight limit = 275 lbs
- Weight of knee = 2 lbs
- Battery life ~ 24 hours
- 36 month warranty



OTTO BOCK C-LEG COMPACT (K2 MPK)

- IP Rating???
- Stance control only. Stumble recovery
- Max weight limit = 275 lbs
- Weight of knee = 2.7 lbs
- Battery life ~ 48 hours
- 36 month warranty



KNEES RANKED BY IP RATING

- Kenevo (IP22): Protection against dripping water
- Rheo (IP34): OK for freshwater splashes. "Withstands exposure to humid and rainy weather conditions without damage or loss of function."
- C-leg (IP54): Should not come into contact with salt water. Ok for freshwater rinse and dry immediately afterward.
- Genium (IP54): Same as C-leg.
- Orion (IP?): "Weatherproof", similar to C-leg and Genium
- Plié (IP67): Can be submersed in shallow fresh water for 30 minutes at a time. Should be dried off after.
- X-3 (IP68): Corrosion resistant coating. OK for fresh/salt/chlorinated water.

KNEES APPROPRIATE FOR RUNNING



Otto Bock X-3

Freedom Innovations Plie



Ossur Rheo

INSURANCE COVERAGE

Show me the money



MEDICARE: LOCAL COVERAGE DETERMINATION (LCD)

- Describes which services are reasonable/covered by Medicare, including who qualifies/what criteria must be met
- "A determination of the type of knee for the prosthesis will be made by the treating physician and/or the prosthetist based upon the functional needs of the beneficiary. Basic lower extremity prostheses include a single axis, constant friction knee. Other prosthetic knees are considered for coverage based upon functional classification."
- Microprocessor knees covered for those patients who are K3 and K4
- Based on previous and current function, desire to ambulate, and medical history

WHEN IS A PATIENT ELIGIBLE FOR A DIFFERENT KNEE?

- Make sure knee is out of warranty before thinking about replacement
- Change in functional status/medical condition (improvement or regression)
- Change in weight
- Knee is broken (irreparable damage)
- Loss
- Needs to be documented in physician's and prosthetist's notes as to reason for replacement vs repair

BLUECROSS POLICY ON MPK. COVERED FOR.....

- Demonstrates need for long distance ambulation with variable cadence OR need for regular ambulation on uneven terrain/ use on stairs AND physical ability to walk "faster than normal walking speed" AND adequate cognitive ability to understand how to use the technology
- Needs to have documentation by "trained prosthetic clinician" and the person doing the evaluation cannot be an employee of the supplier of the device
- Indications: adequate strength and balance, K2 patients if improved stance stability allows increased independence, less fall risk, potential to advance to less restrictive walking device, K3/K4 patients, potential to lessen back pain

BLUECROSS POLICY ON MPK. CONTRA-INDICATIONS

- Condition that prevents successful socket fitting (wound, intractable pain)
- K0, K1, K2 (that would not have the physical ability to benefit from a MPK)
- Hip flexion contracture > 20 degrees
- Long distance/competitive running
- Environmental factors such as excessive moisture and dust, inability to charge the prosthesis, deformity of sound side that would impair ability to stride, limited cognitive ability to use features of MPK

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